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Docket No. GJE-73D1  
Serial No. 10/667,721Remarks

Claims 1-6 are currently pending in the subject application. Favorable consideration of the claims, in view of the remarks set forth herein, is earnestly solicited.

Claims 1 and 6 have been rejected under 35 U.S.C. §102(e) as being anticipated by newly cited Dopheide *et al.* The applicants respectfully traverse this ground for rejection because the cited reference does not disclose or suggest the applicants' advantageous composition that induces apoptosis in reactive T-cells.

The Dopheide *et al.* reference is easily distinguished from the claimed invention because the Dopheide *et al.* proteins stimulate the immune system rather than inducing apoptosis. Dopheide *et al.* are concerned with inducing protective immunity by administering the identified peptides, whereas the present invention relates to the suppression of immunity, by triggering apoptosis and controlled cell death. The compositions are, therefore, in effect, mutually exclusive; one skilled in the art would not, and could not, use an immune suppressant in order to induce protective immunity. Accordingly, the protein defined by Dopheide *et al.* as sequence ID NO:25, or any other protein less than 12 kDa described in the Dopheide *et al.* reference, cannot have a pro-apoptotic activity, and cannot therefore induce apoptosis in reactive T cells.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

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In *Dewey & Almy Chem. Co. v. Mimex Co.*, Judge Learned Hand wrote:

No doctrine of the patent law is better established than that a prior patent . . . to be an anticipation must bear within its four corners adequate directions for the practice [of the subsequent invention] . . . if the earlier disclosure offers no more than a starting point . . . if it does not inform the art without more how to practice the new invention, it has not correspondingly enriched the store of common knowledge, and it is not an anticipation. 124 F.2d 986, 990; 52 USPQ 138 (2<sup>nd</sup> Cir. 1942).

As noted above, the applicants' claims require that the claimed composition must induce apoptosis in reactive T-cells. The Office Action does not identify this critical characteristic in the teachings of the cited reference and, accordingly, an anticipation rejection is improper.

Furthermore, to the extent that the Examiner might be tempted to state that the proteins of the cited reference "inherently" possess the recited properties of the applicants' claimed composition, clearly that is not the case. The applicants respectfully point out that for a claim to be anticipated under the principles of inherency, the subject of a single prior art reference must necessarily function in accordance with the limitations of the claimed subject matter. *In re King*, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Further,

the doctrine of inherency is available only when the prior inherent event can be established as a certainly. That an event may result from a given set of circumstances is not sufficient to establish anticipation. . . . A prior inherent event cannot be established based on speculation, or where a doubt exists (emphasis added). *Ethyl Molded Product Co. v. Betts Package Inc.*, 9 USPQ 2d 1001, 1032-33 (E.D. KY 1988).

As noted above, apoptosis is, in effect, the antithesis of the protective immunity produced by Dopheide *et al.* Thus, the Dopheide *et al.* reference does not disclose, either explicitly or inherently, the compositions of the subject invention. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e).

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In view of the foregoing remarks, and the amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§§1.16, 1.17, or 1.492 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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